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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,101	05/18/2001	Robert D. Mass	3118/1H146US1	9233

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EXAMINER
YU, MISOOK

ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,101	MASS, ROBERT D.	
	Examin r	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 21, and 24-26 are pending and examined on merits.

Claim Rejections - 35 USC § 112

The rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the claims reasonably communicates that detection of HER2 gene amplification is indicative of patient disposed to respond favorably to a HER2 antagonist.

Claim 21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enabling for her2 gene amplification and Herceptin, does not reasonably provide enablement for any other erbB gene antagonist and any other ErbB antagonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant argues that this rejection is moot because the limitation in non-rejected claim 23 is incorporated into the base claim 21. This argument is not persuasive because the amended claims are now drawn to method of screening cancer patients by determining HER2 gene amplification as the parameter for favorable response to a HER2 antagonist and then treating the patients with a HER2 antagonist. The specification teaches only HER2 antibody as a HER2 antagonist capable of treating breast cancer but does not teach how to make any other antagonist that could be used in the treatment step of the claim. Ross et al (#5 of IDS filed 7-26-2002, 1998, Stem Cell, vol. 16, pages 413-428) or Ross et al (#209 of IDS

filed 2-7-2002, 1997, Cancer, vol., 79, pages 2162-2170) teach that breast cancer treatment is not trial and requires undue experimentation. Considering the state of art in breast cancer treatment, limited guidance and no working examples of breast cancer treatment with any other HER2 antagonist other than the antibody in the specification, it is concluded that undue experimentation is required to practice the full scope of the invention.

Claim Rejections - 35 USC § 102

The rejection of claim 21 under 35 U.S.C. 102(b) as being anticipated by either Ross et al (Ross I, #5 of IDS filed 7-26-2002, 1998, Stem Cell, vol. 16, pages 413-428) or Ross et al (Ross II, #209 of IDS filed 2-7-2002, 1997, Cancer, vol., 79, pages 2162-2170) is withdrawn because Ross I teaches detection steps but does not teach the treatment step of the amended claim and Ross II teaches the treatment step but does not teach that the instantly recited detection step of the amended claim.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

Claims 21, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The purpose stated in the preamble of the base claim 21 and the active steps of the claims are not same, which makes the claims confusing and therefore indefinate. The preamble of claim 21 says that the instantly claimed invention is drawn to method of identifying a patient (screening candidate patients) disposed to respond favorably to a

HER2 antagonist. However, the active step of the amended claim 21 says "detecting" and then "treating".

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is interpreted as drawn to method of treating breast cancer using a genus of HER2 antagonist. The specification provides evidence for only one species, HER2 antibody. Based on one species, one cannot predict additional species capable of treating breast cancer. Since the entire genus includes a large number of unpredictable species, possession of only one species is not seen as sufficient to reasonably convey possession of the entire genus. It is concluded that applicant adequately describes HER2 antibody capable of treating breast cancer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Godolphin et al (1996, Oncogene vol. 13, pages 63-72) Ross II (cited above), or Persons et al (IDS #4, Jan. 2000, Annals of Clinical and Laboratory Science vol. 30, pages 41-8) for the detection step, and over any one of

Ross I (cited above), Baselga et al (IDS #124, 1996, Journal of Clinical Oncology vol. 14, pages 737-44), Baselga et al (1999, Semin Oncol vol vol. 26, No. 4 supp 12, pages 87-83) for the treating step.

The claims are interpreted as drawn to method of screening breast cancer patients who might respond favorably to Her2 antibody treatment by detecting Her2 amplification using FISH and then treating patients with her2 amplication using Her2 antibody.

Any one of of Godolphin et al, Ross II, or Persons et al teaches Her2 gene amplification using FISH is superior to immunochemistry for assessing Her2 status in patients with breast cancer before a clinical decision. Any one of Ross I, Baselga et al (1996), or Baselga et al (1999) teaches the clinical decision whether or not to treat breast cancer patients with Her2 antibody is based on Her2 status i.e., patients have been selected for Her2 antibody treatment when said patients overexpress Her2. Assessing Her2 status is determined using immunochemistry. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute FISH technique for assessing the Her2 status before the treatment.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Godolphin et al, Persons et al, or Ross II for the determination step as applied to claims 21, 24, and 26 above, and further in view of Baselga et al (1999, cited above) for the treating step.

Baselga et al teach Herceptin has been shown efficacy in treating breast cancer overexpressing Her2.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
August 13, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600